

DRAFT OPEN SESSION AGENDA
NEUROLOGICAL DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE

Sixteenth Meeting

**Hilton Washington North/Gaithersburg
Ballroom Salons, A, B, C, and D
620 Perry Parkway
Gaithersburg, Maryland
February 23, 2003**

Panel Chairperson, acting
Kyra J. Becker, M.D.

Executive Secretary
Janet L. Scudiero, M.S.

- 9:30 am Call to Order**
Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions
Update Since the August 5, 2003 Meeting
Neil R. Ogden, Chief, General Surgery Devices Branch
- 9:45 am Open Public Hearing***, up to 60 minutes
- 10:45 am Concentric Medical MERCI 510(k) K03-3736**
Kevin F. MacDonald, Vice President Clinical and Regulatory Affairs
Gene Sung, MD, MPH, Director, Neurocritical Care and Stroke Program, USC
Wade Smith, MD, PhD, Director, Neurovascular Service, UCSF
Gary Duckwiler, MD, Professor of Radiology, UCLA
- 11:45 am FDA Presentation**
Clinical Review: Michael Schlosser, M.D.
Statistical Review: Judy S. Chen, M.S.
- 12:45 pm Lunch**
- 1:30 am Panel Deliberations**
Clinical Review: Mary E. Jensen, M.D.
Statistical Review: Jonas H. Ellenberg, Ph.D.
- 2:30 pm Break**
- 2:45 pm FDA and Sponsor Summations**, up to 15 minutes each
- 3:15 pm FDA Questions and Concluding Comments**
- 5:00 pm Adjournment**

*** Open Public Hearings** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair

will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing